Tiger Medical Group

510(k) Summary

JAN 2 5 2011

This summary of 510K safety and effectiveness information is being submitted in accrodance with the requirements of 21 CFR 807.92.

The assigned 510K number is K102713

1. Submitter's Identification:

Tiger Medical Products Ltd
Liulin Tower, STE 1910
1 Huai Hai Zhong Road
Shanghai 200021
P.R.China

Contact:

Maggie Zhong
Tel:+86-21-33907930
Fax:+86-21-33907932
Mail: maggie-zhong2001@vip.sina.com

Date of Summary: March 8th, 2010

2. Device Name:

Tiger Surgical Mask

3. Classification Name: Surgical Mask

4.. Device Description

The Tiger surgical mask SFM0001 (colors: blue) is flat pleated by 3-ply masks with outer layer and inner layers (spunbonded polypropylene) that sandwich a meltbown polypropylene filter material; Ear-loops are made of urethane elastic fiber for free elastic loops. The nose piece is white aluminum strip with PP covering.

All of the materials used in the construction of the Tiger flat surgical Masks are being used in currently marketed devices (see predicate information). All items are no–sterilize and only for single use.

5. Intended Use:

Tiger surgical mask SFM0001 is intended for single use by operating room personnel or general health care workers for protection against microscopic organisms, body fluids and particulates. These would include use procedure mask, isolation mask or dental

6. Comparison to Predicate Devices

Tiger surgical mask SFM0001(color: blue) substantially equivalent is safety and effectiveness to the predicate devices.

Tucker & Associates company-K022256 Surgical face masks white, yellow, pink, blue and green

Prestige Ameritech-K061716 Prestige Ameritech Face Mask (multiple labels)

K102713

Performance Characteristics	Test method	Acceptance criteria/result	Predicate device results	Predicate device results
		Tiger surgical mask SFM0001	K061716	K022256
Fluid resistance	ASTM 1862	31 of 32 Pass at 120mmHg	29 of 32 pass	No visual penetration
Particulate Filtration Efficiency	ASTM F2299	>99.9% at 2.7μm	2.0 microns	98.5% at 0.1 microns
Bacterial Filtration Efficiency	ASTM F2101	99.86%	99.6%	97.9%
Flammability Class	16CFR 1610	1	1	2
Delta-P	Mil M36954C	3.78	2.6	1.8
Biocompatibility	ISO10993-1	Cytotoxictiy: no cyctotoxtial potential	N/A	N/A
		Sensitization: negligible	N/A	N/A
		Irritation: No reactions	N/A	N/A

Discussion of Non-clinical Test Performed for Determination of Substantial Equivalence are as follows:

I. NELSON Fluid Resistance-Resistance of Liquid (Synthetic Blood Penetration Resistance) ASTM F 1862

II. NELSON Bacterial Filtration Efficiency (BFE) test ASTMF2101

III. NELSON Particulate Filtration Efficiency (Latex Particule Challenge ASTM F2299)

IV. NELSON Flammability, Complied with 16 CFR 1610 Class I,

V. TOXIKION Biocompatibility per ISO 10993

It is our conclusion that performance testing meet all relevant requirements of the aforementioned test standard.

Discussion of Clinical Tests Performed.

Not Applicable

7. Conclusions

Tiger surgical mask SFM0001 has the same intended use and technology characteristics as the predicate devices (K022256,K061716). Moreover, the bench testing contained in this submission supplied demonstrate that the technological characteristics do not raise any new question of safety or effectiveness. Therefore, the Tiger SFM0001 flat surgical mask is substantially equivalent to the predicate devices.

LIU LIN TOWER, SUITE 1910-1911•1 HUAI HAI ZHONG ROAD•SHANGHAI 200021 CHINA
TEL: +86-21-6386-6300 FAX: +86-21-6386-5086
WWW.TIGERMEDICALPRODUCTS.COM

Tiger Medical Products Ltd
Liulin Tower, STE 1910, 1 Huai Hai Zhong Road, Shanghai, 200021
Tel: 86-21-63866300-134 Fax: 86-21-63865086

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Standards & Regulations
Declaration of Conformity

As manufacturer **Tiger Medical Products Ltd**
Liulin Tower, STE 1910
1 Huai Hai Zhong Road
Shanghai 200021
P.R.China

We declare that SFM0001 flat surgical masks are conforms to standards/ regulations listed herein according to FDA requirements.

Standards & regulations declaration of conformity

Reference	Description	Test Laboratories	Comments
ASTM F1862	Synthetic Blood Penetration Resistance	Nelson Laboratories	Refer to test report
ASTM F2101-01	Bacterial Filtration Efficiency(BFE) and Delta-P	Nelson Laboratories	Refer to test report
ASTM F2299	Particulate Filtration Efficiency	Nelson Laboratories	Refer to test report
16 CFR 1610	Flammability 16	Nelson Laboratories	Refer to test report
ISO10993-5	Cytotoxicity	Toxikon Corporation	Refer to test report
ISO10993-10	Irritation & Sensitization	Toxikon Corporation	Refer to test report

(Signature)

(Typed Name)
Elaine M Fong

(Date)
March 8, 2010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room --WO66-G609
Silver Spring, MD 20993-0002

Ms. Maggie Zhong
Consultant
Tiger Medical Products, Limited
Liulin Tower, STE 1910
1 Huai Hai Zhong Road
Shanghai 200021
P.R. China

JAN 25 2011

Re: K102713
Trade/Device Name: Tiger Surgical Mask for single use
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: December 23, 2010
Received: January 10, 2011

Dear Ms. Zhong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

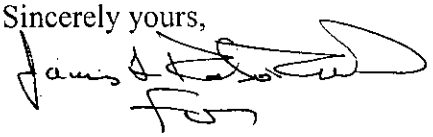
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment A

INDICATIONS FOR USE

510(k) NUMBER (IF KNOWN): K102713

APPLICANT: **Tiger Medical Products Ltd**

DEVICE NAME: **Tiger Surgical Mask for single use**

INDICATION FOR USE:
The Tiger SFM0001 surgical mask is intended for single use by operating room personnel and other health care workers to protect both the patients and the health care workers from transfer of microorganisms, blood and body fluids, and airborne particulate materials.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie-Wilbon
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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